

REMARKS

Applicant respectfully requests reconsideration. Claims 35-51 were previously pending in this application. Claims 35, 36, 39 and 43 are amended herein. Claims 37 and 45 are canceled herein without prejudice or disclaimer. As a result, claims 35-36, 38-44 and 46-51 are still pending for examination with claim 35 being an independent claim. No new matter has been added.

Title of the invention

The title of the invention was objected to for not being descriptive. In response, Applicant herein amended the title to “METHODS OF UPMODULATING ADAPTIVE IMMUNE RESPONSE USING ANTI-PD1 ANTIBODIES” so as to clearly indicate the invention to which the claims are directed. Entry of the amended title is respectfully requested.

Rejection Under 35 U.S.C. 112 – Indefiniteness

Claims 35-44 and 46-51 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. Specifically, the Examiner indicated that the recitation of “modulating” rendered the claims indefinite because the term allegedly is “ambiguous as to the direction (positive or negative) or degree of said modulating” (Office Action page 3, item 4A).

Without particularly acquiescing to the contention, Applicant has amended the claims herein to refer to “upmodulating” of the adaptive immune response. Basis for this recitation is found in the specification as filed, for example, at paragraph [084] and Example 9. Applicant believes that this amendment should address the Examiner’s rejection.

The Examiner further objected to the term “PD-L” as allegedly being unclear as to whether it was intended to encompass PD-L1 or PD-L2, or both. In response, Applicant has amended the claim to now recite “PD-L1 or PD-L2” thus overcoming the Examiner’s objection. Basis for this amendment is found, at least, at paragraph [006] of the specification as filed.

Based on the foregoing, Applicant asserts that the claims are now in compliance with 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of the rejection is respectfully solicited.

Rejection Under 35 U.S.C. 112 – Enablement

Claim 43 has been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Specifically, the Examiner argued that to practice the claimed invention, antibodies Pd1-17, PD1-28, PD1-33, PD1-35 and PD1-F2 are required, and as such, “they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification” (Office Action page 4, item 6). The Examiner further stated that if these antibodies are not obtainable or available, the enablement requirements of 35 U.S.C. § 112 “may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies.”

Applicant has amended claim 43 to refer to these antibodies in terms of the sequences of their light and heavy chains and to refer to the relevant SEQ ID NOs. In view of the recitation in the claims of sequence identifiers, it is not believed that deposits of these antibodies are required. The skilled person has sufficient information from the recited sequences to reproduce the antibodies. Accordingly, the Examiner is kindly requested to withdraw his rejection made under 35 U.S.C. § 112, first paragraph.

Claims 35-42, 44 and 46-51 were further rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the claimed method utilizing an antibody comprising all six CDRs (or both heavy and light chain variable regions) of one of antibodies PD1-17, PD1-28, PD1-33, PD1-35, and PD1-F2, wherein the antibody specifically binds to PD-1 of amino acid sequence SEQ ID NO: 41 or 56, allegedly does not reasonably provide enablement for:

- A. an antibody defined by a sequence of a single complementarity-determining region (CDR) or a single variable region; or

B. an antibody which specifically binds to an amino acid sequence that is at least 95% identical to any sequence of at least 100 of contiguous amino acids of SEQ ID NO: 41 or 56. According to the Examiner, “the formation of an intact antigen-binding site generally requires all six CDRs” (emphasis in original; Office Action page 6, item 7A).

Applicant does not wholly agree with the Examiner’s position, particularly in light of the highly developed nature of the antibody technology, also in view of *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004). However, for the benefit of advancing prosecution, Applicant has herein amended claim 35 to include all six CDRs in the context of the VL and VH domains, and to recite specifically the three CDRs that are within each of the VL and VH domains. Applicant believes that the amendment presented herein addresses the Examiner’s objection and that claim 35 is now believed to be in a format in accordance with the Office’s practice for antibody claims. It is therefore respectfully requested that the rejection be withdrawn. The CDRs are as set out in the table on page 11 of the specification as filed.

Rejection Under 35 U.S.C. 112 – Written Description

Claims 35 and 37 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner objected to the recitation “at least 95% identical.”

Claim 37 has been canceled herein without prejudice or disclaimer. As such, this rejection is moot. Accordingly, Applicant respectfully request the rejection made under 35 U.S.C. § 112, first paragraph be withdrawn.

Rejection Under 35 U.S.C. 102

Claims 35-44 and 46-51 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Wood et al. (US Patent 6,808,701; filed 08/23/2000; priority dated 08/23/1999; see entire document), as evidenced by the instant specification at pages 13-14. According to the Examiner, Wood et al. refers to antibody PD1-17, which is an anti-PD1 antibody, and that Wood et al. teaches

a method of down-modulating the immune response using anti-PD1 antibodies and therefore anticipates the claimed invention.

Applicant respectfully disagrees. Firstly, it should be noted that claim 35 as currently amended, does not refer to sequences comprised within antibody PD1-17. Thus, the specific sequences of CDRs provided in claim 35 are not anticipated by the teaching of Wood et al. Secondly, the instant invention relates to a method of *up-regulating* the immune response, whereas Wood et al. teaches a method of *down-regulating* the immune response. Thus, the cited reference does not anticipate the subject claims. Accordingly, Applicant submits that the claimed invention is novel and respectfully requests withdrawal of the rejection made under 35 U.S.C. § 102(e).

Double Patenting Rejection

Claims 35-44 and 46-51 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,808,710 and claims 1-7 of U.S. Patent No. 7,029,674.

By the amendment presented herein, Applicant believes that the nonstatutory obviousness-type double patenting rejection over the cited patents is overcome. However, Applicant requests that the Examiner kindly notify Applicant in the event that the Examiner believes the rejection still stands.

Claims 35-44 and 46-51 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application USSN 11/357,434 and claims 1-26 of copending Application USSN 11/514,328.

Applicant believes that the rejection is overcome by the current amendments. It is respectfully requested that the Examiner reconsider and withdraw the nonstatutory obviousness-type double patenting rejections.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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